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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,196	08/02/2001	Irma H. Russo	13254-00012	6024

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WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,196	RUSSO ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45,55-60,63-65,70-78 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45, 55-60, 63-65, 70-78, 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00.

DETAILED ACTION

Applicant's submission filed on 28 April 2005 is acknowledged. Claims 45, 55-60, 63-65, 70-78, and 80 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections, Withdrawn

The objection of claim 45 is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

The rejection of claims 45, 55-58, 70-76 under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) is **withdrawn** in view of the newly amended base claim now recite "post menopausal woman", which the prior art of record does not teach.

Claims 45, 55-58, 60, 63, 64, 70-76 are rejected under 35 U.S.C. **103(a)** as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16).

Claim 45 (the base claim of the claimed invention) is drawn to method of treating clinically manifest mammary tumors with an active step of administering an effective

amount of hCG to postmenopausal woman to inhibit proliferation of mammary tumors, claim 55 further limits the tumor to be a primary tumor, claim 56 further limits the tumor to be a non-invasive carcinoma, claim 57 further limits the carcinoma to be a in situ or lobular carcinoma in situ, claim 58 further limits the tumor to be invasive carcinoma, claim 60 further limits the mammary tumor to be metastatic mammary tumors, claim 63 further limits with an active step of administering an effective amount of hCG with at least other treatment, wherein said at least other treatment being surgery or chemotherapy (claim 64), claims 70-72 further limit the amount to be 50 to 20,000 IU per day, clams 73-76 further limit hCG to be administered every second day, 3 times per week, for several weeks following the first dose, and at least 12 weeks respectively,

Applicant argues that the currently amended base claim 45 is not obvious over any one of Srivastava et al (199), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) because the references alone or in combination teach or suggest a method of treating clinically manifest mammary tumors in postmenopausal women by detecting the mammary tumor in the host, then initiating and carrying out a dose regimen of hCG in amount and for a time effective to inhibit mammary tumor cell proliferation. The statement by Stravastava (i.e. "those of agents like hCG that induce apoptosis may constitute a useful approach for the prevention and therapy of breast cancer") constitutes merely an invitation to experiment, and does not teach or suggest the method as presently claimed, with all limitations, nor impart any expectation of success in practicing the claimed method. There is nothing in any of the references to motivate

the skilled artisan to modify or combine any teaching of these references to arrive at a method of treating clinically manifest tumors in post-menopausal women. As for Grattarola reference, applicant argues that in contrast to the instantly claimed invention of method of treating patients who are not free of recurrence, Grattarola reference teaches method of administering hCG to mammary cancer patients that were free of any recurrence of the cancer.

These arguments have been fully considered but found unpersuasive for the following reasons. As for applicant's argument of one of ordinary skill in the art not being able to arrive at the instantly claimed invention with a reasonable expectation of success given the teachings of any one of the primary references, it is noted that any of the primary references teaches the preferred embodiment as recited in the instant claims 70, and 71. For example, Srivastava et al., teach at the 1st line of the abstract "Human chorionic gonadotropin (hCG) inhibits progression of 7,12-dimethylbenz[*a*]anthracene (DMBA) induced mammary carcinomas." Srivastava et al., teach method of treating clinically manifest mammary tumors (i.e. DMBA-induced non invasive, and invasive mammary carcinoma) by administering 100 IU hCG obtained from Sigma to a host for 40 days to inhibit proliferation of mammary tumor cells. Note Figs. 1 and, Materials and methods at page 1800, Table I and II at page 1801. In addition, Srivastava et al., teach the identical time schedule (effective to inhibit mammary tumor cell proliferation) as recited in the instant claims 73-75. Therefore, selecting these time schedules and dose regime already proven to be effective for inhibiting proliferation of clinically manifest mammary tumors (i.e. breast carcinoma) is

obvious and one of ordinary skill in the art would have been able to arrive with a reasonable expectation of success.

Further, as stated in the previous Office actions, Russo et al (IDS AS) also teach method of treating/preventing DMBA-induced mammary tumor (non invasive, invasive, carcinoma) by administering 100 IU hCG. Note Fig. 1 and 2, and Table 1. Russo et al (IDS AT) also method of treating/preventing DMBA-induced mammary tumor (non invasive, invasive, carcinoma) by administering 100 IU hCG. Note Experimental protocol at page 2343, Tables I-III.

As for the argument that the claimed invention is a method of treating patients who are not free of recurrence, the claims as currently drafted does not say anything about "treating patients who are not free of recurrence". In other words applicant is arguing a limitation not present in the claims. In addition, claims 45 and 64 as currently construed say that surgery could come before hCG treatment because the claims uses the transitional phrase "comprising" without any order of the different treatments being involved, once the clinically manifest tumor is detected. In other words, the limitation "clinically manifest mammary tumor" could be just before the removal of the involved breast by surgery, which is taught by Grattarola reference. Therefore, applicant argument that the menopausal women who are free of recurrence in Grattarola reference received appears to be irrelevant issue because the claimed invention does not specify the order of treatment (i.e. surgery comes first, or hCG comes first once the tumor is detected). The main reason Grattarola reference is cited as the secondary reference is because the primary reference does not teach postmenopausal woman

develops clinically manifest mammary tumor. However, the secondary reference (i.e. Grattarola reference that applicant criticize not teaching the population as recited and also criticizing as not teaching the hCG being used for other purpose than the recited purpose used in the instantly claimed method) teaches that a menopausal woman also develop clinically manifest tumors that requires treatment. In the case of Grattarola reference, the treatment was surgery as recited in the instant claim 64 as "one of the at least one other treatment for clinically manifest mammary tumors" (note the instant claim 63).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to treat treating a clinically manifest mammary tumor after detecting a clinical manifest mammary tumor in a postmenopausal woman since Grattarola reference teaches a postmenopausal woman develops a clinically manifest mammary, and at least one treatment for a clinical manifest mammary tumor in a postmenopausal woman is surgery, followed by administering 100 IU hCG per day as taught by any one of the primary reference with a reasonable expectation of success since any of the three primary references teach how to obtain the active ingredient, i.e. hCG that causes apoptosis of mammary cells, thus inhibiting proliferation of mammary tumor cells. Any one of the primary reference teach how to administer the active ingredient in vivo subject. With the doses in claims 70-72, and the administration schedules in claims 73-76, 100 IU for several weeks are used in all of the three references for the model animals, thus adjusting other doses for different body weight,

for example, and also adjusting different schedules, for example based on progress of the treatment are well within the level of ordinary skill in the art.

Claim 45, 55-58, **59**, 60, 63, 64, 70-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7), in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16), and further in view of Silverstein et al., of record (1994, Cancer, vol. 73, pages 1673-7, abstract only). Note Grattarola of record is newly used as the secondary reference because of the new limitation of "postmenopausal woman" in the amended base claim.

See interpretation of claims 45, 55-58, 60, 63, 64, and 70-76 above. Claim 59 not rejected above is interpreted as drawn to method of treating tubular or lobular mammary carcinoma by administering hCG in a postmenopausal woman.

Applicant argues that the claimed invention is a method of treating clinically manifest mammary tumor in postmenopausal women, and the primary references do not teach or suggest this method, and the deficiency in the primary references are not supplied by Silverstein. Applicant argues that Silverstein do not teach or suggest that hCG could be used to treat clinically manifest tubular or lobular invasive carcinoma in postmenopausal women. Applicant argues that all the limitation of the claims are not taught by the prior art of record, and one of ordinary skill in the art would not be

motivated to modify or combine any of these references to arrive at the claimed invention with a reasonable expectation of success.

These arguments have been fully considered but found unpersuasive for the following reasons. As stated above, and in the previous Office action, any one of the primary references teaches an amount and time period effective to inhibit proliferation of mammary tumor cells. The primary references do not teach whether a postmenopausal woman develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification. However, the secondary reference (Grattarola) teaches that a postmenopausal woman also develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification, and at least one method of treating a postmenopausal woman with a clinically manifest mammary tumor is surgery (see above for detail about what the secondary reference teaches). Neither the primary nor the secondary reference teaches tubular or lobular mammary carcinoma. However, Silverstein et al., teach that tubular or lobular invasive breast mammary carcinoma is also a mammary tumor, and breast cancer staging is well known in the art before the effective filing date of the instant application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to select which patients has the specifically recited stage of breast cancer and treat with hCG and other effective treatment (i.e. surgery in the case of Grattarola) with a reasonable expectation of success given the primary references teach all the dose and time schedule effective for inhibiting proliferation of mammary tumor.

Claims 45, 55-58, **65**, 60, 63, 64, 70-76 are rejected under 35 U.S.C. **103(a)** as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16), and further in view of n view of Mgbonyebi et al (1997, IDS AL). Note Grattarola of record is newly used as the secondary reference because of the new limitation of "postmenopausal woman" in the amended base claim.

See interpretation of claims 45, 55-58, 60, 63, 64, 70-76 above.

Claim 65 not rejected above is interpreted as drawn to method of treating clinically manifest mammary tumors in a postmenopausal woman by administering the hCG to estrogen positive mammary tumor.

Applicant argues that the claimed invention is a method of treating clinically manifest mammary tumor in postmenopausal women, and the primary references do not teach or suggest this method, and the deficiency in the primary references are not supplied by Mgbonyebi et al. Applicant argues that Mgbonyebi et al., do not teach or suggest that hCG could be used to treat clinically manifest estrogen positive mammary tumor in postmenopausal women. Applicant argues that all the limitation of the claims are not taught by the prior art of record, and one of ordinary skill in the art would not be motivated to modify or combine any of these references to arrive at the claimed invention with a reasonable expectation of success.

These arguments have been fully considered but found unpersuasive for the following reasons. As stated above, and in the previous Office action, any one of the primary references teaches an amount and time period effective to inhibit proliferation of mammary tumor cells. The primary references do not teach whether a postmenopausal woman develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification. However, the secondary reference (Grattarola) teaches that a postmenopausal woman also develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification, and at least one method of treating a postmenopausal woman with a clinically manifest mammary tumor is surgery (see above for detail about what the secondary reference teaches). Neither the primary nor the secondary reference teaches estrogen-positive mammary tumors. However, Mgbonyebi et al (1997, IDS AL) teach hCG is effective in inhibiting growth of estrogen positive breast cancer cells, Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to detect which breast cancer is estrogen positive and practice the instantly claimed invention with reasonable expectation of success.

Claims 45, 55-58, 60, 63, 64, 70-76, and **77** are rejected under 35 U.S.C. **103(a)** as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62,

pages 2343-7) in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16) and further in view of Saal et al., of record, Fertil Steril. 1991 Aug;56(2):225-9. Note Grattarola of record is newly used as the secondary reference because of the new limitation of "postmenopausal woman" in the amended base claim.

Claim 77 not rejected above is interpreted as drawn to method of treating clinically manifest mammary tumors in a postmenopausal woman by administering the active ingredient, i.e. hCG subcutaneously.

Applicant argues that the claimed invention is a method of treating clinically manifest mammary tumor in postmenopausal women, and the primary references do not teach or suggest this method, and the deficiency in the primary references are not supplied by Saal et al. Applicant argues that all the limitation of the claims are not taught by the prior art of record, and one of ordinary skill in the art would not be motivated to modify or combine any of these references to arrive at the claimed invention with a reasonable expectation of success.

These arguments have been fully considered but found unpersuasive for the following reasons. As stated above, and in the previous Office action, any one of the primary references teaches an amount and time period effective to inhibit proliferation of mammary tumor cells. The primary references do not teach whether a postmenopausal woman develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification. However, the secondary reference (Grattarola) teaches that a postmenopausal woman also develops

a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification, and at least one method of treating a postmenopausal woman with a clinically manifest mammary tumor is surgery (see above for detail about what the secondary reference teaches). Neither the primary nor the secondary reference teaches injecting hCG subcutaneously. However, However, Saal et al., teach administering hCG subcutaneously at page 226 under the heading "Study Protocol". Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to select subcutaneous injection method to administer hCG with a reasonable expectation of success.

Claims 45, 55-58, 60, 63, 64, 70-76, and **78** are rejected under 35 U.S.C. **103(a)** as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16) and further in view of any one of Platanias et al., of record (J Biol Chem. 1998 Mar 6;273:5577-81), Oberg et al., of record (1989, J Natl Cancer Inst., vol. 81, pages 531-5), Recchia et al., of record (Clin Ter. 1998 May-Jun;149:203-8), or Robinson et al (1990, Breast Cancer Res. Treat., vol. 15, pages 95-101, abstract only). Note Grattarola of record is newly used as the secondary reference because of the new limitation of "postmenopausal woman" in the amended base claim.

See interpretation of claims 45, 55-58, 60, 63, 64, 70-76 above.

Claim 78 not rejected above is interpreted as drawn to method of treating clinically manifest mammary tumor in a postmenopausal woman by administering the active ingredient, i.e. hCG in combination with Type 1 interferon.

Applicant argues that the claimed invention is a method of treating clinically manifest mammary tumor in postmenopausal women, and the primary references do not teach or suggest this method, and the deficiency in the primary references are not supplied by any one of any one of Platanias et al., of record (J Biol Chem. 1998 Mar 6;273:5577-81), Oberg et al., of record (1989, J Natl Cancer Inst., vol. 81, pages 531-5), Recchia et al., of record (Clin Ter. 1998 May-Jun;149:203-8), or Robinson et al (1990, Breast Cancer Res. Treat., vol. 15, pages 95-101, abstract only). Applicant argues any one of Platanias et al., of record (J Biol Chem. 1998 Mar 6;273:5577-81), Oberg et al., of record (1989, J Natl Cancer Inst., vol. 81, pages 531-5), Recchia et al., of record (Clin Ter. 1998 May-Jun;149:203-8), or Robinson et al (1990, Breast Cancer Res. Treat., vol. 15, pages 95-101, abstract only) does not teach or suggest that hCG could be used in combination with Type 1 interferon to treat clinically manifest mammary tumors in postmenopausal woman. Applicant argues that all the limitation of the claims are not taught by the prior art of record, and one of ordinary skill in the art would not be motivated to modify or combine any of these references to arrive at the claimed invention with a reasonable expectation of success.

These arguments have been fully considered but found unpersuasive for the following reasons. As stated above, and in the previous Office action, any one of the primary references teaches an amount and time period effective to inhibit proliferation of

mammary tumor cells. The primary references do not teach whether a postmenopausal woman develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification. However, the secondary reference (Grattarola) teaches that a postmenopausal woman also develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification, and at least one method of treating a postmenopausal woman with a clinically manifest mammary tumor is surgery (see above for detail about what the secondary reference teaches). Neither the primary nor the secondary reference teaches hCG treatment in combination with Type 1 interferon.

However, any one of Platanias et al of record, Oberg et al of record, or Recchia et al of record, teaches how to make and use Type I interferon for anti-proliferative effects (i.e. to inhibit proliferation of cells).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use Type I interferon known to have anti-tumor effect in combination with hCG with reasonable expectation of success. Each of the two active ingredients have been taught in the prior art to be therapeutically effective to inhibit proliferation of cells, and therefore the instant situation is amenable to an analysis according to In re Kerkhoven, 205USPQ 1069 (CCPA 1980) - it is a prima facie obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill in the art would be motivated to

combine the teachings because the primary references of record has shown that hCG is effective to inhibit proliferation of mammary tumor cells, and the tertiary reference teaches that Type 1 interferon is also useful in inhibiting proliferation of cells.

Claims 45, 55-58, 60, 63, 64, 70-76, and **80** are rejected under 35 U.S.C. **103(a)** as being unpatentable over any one of Srivastava et al (1997, IDS AX, cited in ISR, Carcinogenesis, vol. 18, pages 1799-1808), Russo et al (1990, IDS AS, J. Natl, Cancer Inst. Vol. 82, pages 1286-1287), or Russo et al (1990, IDS AT, Br. J. Cancer, vol. 62, pages 2343-7) in view of Grattarola of record (1976, Journal of the National Cancer Institute, vol. 56, pages 11-16) and further in view of in view of Sigma catalog of record (1995, page 263 only). Note Grattarola of record is newly used as the secondary reference because of the new limitation of "postmenopausal woman" in the amended base claim.

Claim 80 not rejected above is drawn to the method using recombinant hCG for inhibiting proliferation of mammary tumor cells in a postmenopausal woman.

Applicant argues that the claimed invention is a method of treating clinically manifest mammary tumor in postmenopausal women, and the primary references do not teach or suggest this method, and the deficiency in the primary references are not supplied by the Sigma catalog of record. Applicant argues the Sigma catalog of record does not teach or suggest that hCG could be used in treating to treat clinically manifest mammary tumors in postmenopausal woman. Applicant argues that all the limitation of the claims are not taught by the prior art of record, and one of ordinary skill in the art

would not be motivated to modify or combine any of these references to arrive at the claimed invention with a reasonable expectation of success.

These arguments have been fully considered but found unpersuasive for the following reasons. As stated above, and in the previous Office action, any one of the primary references teaches an amount and time period effective to inhibit proliferation of mammary tumor cells. The primary references do not teach whether a postmenopausal woman develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification. However, the secondary reference (Grattarola) teaches that a postmenopausal woman also develops a clinically manifest mammary tumor that could be detected by the method described at page 9 lines 24-32 of the instant specification, and at least one method of treating a postmenopausal woman with a clinically manifest mammary tumor is surgery (see above for detail about what the secondary reference teaches). Neither the primary nor the secondary reference teaches hCG is a recombinant hCG. However, Sigma catalog says that the recombinant hCG is commercially available, therefore it is the Office's position that claim 80 is an obvious variation of the base claim and one in ordinary skill would have practiced the instantly claimed invention with reasonable expectation of success before the effective filing date of instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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MISOOK YU, Ph.D
Examiner
Art Unit 1642